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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,049	07/24/2001	Thomas G. Rehberger	362.003	4550

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/03/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/912,049

Applicant(s)
Rehberger et al.

Examiner
Irene Marx

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 28, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 2, and 30-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-29 and 41-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5,8 6) ☐ Other:

The amendment and election without traverse filed 10/28/02 is acknowledged. Claims 3-29 and 41-64 are being considered on the merits because these claims read on the claimed invention. Claims 1, 2, and 30-40 are withdrawn from consideration.

To conform with standard practice and for the sake of clarity, dependent claims should be amended to start with --The-- rather than "A".

The disclosure is objected to because of the following informalities: At page 10, the accession numbers of the deposits are missing. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-29 and 41-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-9, 15-16, and 41-64 are vague, indefinite and confusing in that the sole designation of the microorganisms by an internal strain number, which is arbitrary and creates ambiguity in the claims. For example, the microorganisms disclosed in this application could be designated by some other arbitrary means, or the assignment of the strain number could be arbitrarily changed to designate another strain or microorganism. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to the deposit accession number of the claimed strain(s) would obviate this rejection.

Claims 10-29 and 46-48 are vague, indefinite and confusing in that there is no claim designated step to ensure that the milk has more protein, more fat and more solids non-fat as well as increases energy balance, plasma leptin level and plasma non-esterified fatty acids levels, since the method encompasses feeding the same microorganism to the same subject in the same amount to obtain substantially different effects. Do different strains have different effects or do

all strains have these claim designated effects? How is the desired effect obtained? Clarification is required.

Claims 3 and 15 are vague and indefinite in the recitation of "genetic equivalents thereof", since the nature and extent of "equivalence" are unclear in this context.

Claims 14 and 15 are vague and indefinite in that it is unclear which of the recited strains "comprise" *P. acidipropionici* or *P. jensenii* or genetic equivalents thereof.

Claims 10-29, 41-44, 46-48, 57-60 and 62-64 are vague and indefinite in the use of words of degree as a limitation such as "increased", "enhanced", "higher percent"; "substantially greater percent".

When a word of degree is used as a limitation, it is necessary to determine whether the specification provides some standard for measuring that degree. See *Seattle Box Company, Inc. V. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). In this case, the specification does not enable one skilled in the art to reasonably establish what may be construed as being within the metes and bounds of the word of degree. Therefore, one of ordinary skill in the art would not be apprised as to the claimed invention's scope when the claims are read in light of the specification. See *Ex parte Oetiker*, 23 USPQ2d 1641.

In addition, there is no clear indication of the nature and amount of bacteria to be fed to achieve the results as indicated.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-9, 15 and 41-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ particular strains of *Propionibacterium*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 10 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements

and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-29 and 41-64 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rehberger *et al.*.

The claims are drawn to a process of feeding a ruminant with various *Propionibacterium* strains.

The cited reference discloses a process of feeding a ruminant with various *Propionibacterium* strains at least one of which appears to be identical to the strains cultured in the presently claimed process or is a genetic equivalent thereof (see, e.g., Table I). At least one of the referenced microorganisms appear to be identical to the presently claimed strains at least with

respect to genetic equivalents and the disclosed process of feeding is considered to anticipate the claimed process since the *Propionibacterium* strains used in the process are disclosed as having similar beneficial effects on ruminants when added to feed and are of the same class as that of the microorganisms cultured herein. Consequently, the claimed process appears to be anticipated by the reference. The proliferation of the bacteria, as well as the effects on milk productivity, its content of fat, protein etc., and of increasing energy balance, plasma leptin level and plasma non-esterified fatty acid levels in the animal is inherent in the process of feeding certain *Propionibacterium* strains.

In the alternative, even if at least one of the claimed microorganisms is not identical to at least one of the referenced microorganism with regard to some unidentified characteristics, the differences between the process disclosed and that which is claimed are considered to be so slight that the referenced process is likely to use strains possessing the same characteristics of the claimed microorganisms and have the same effectiveness particularly in view of the similar characteristics which the microorganisms have been shown to share. Thus the claimed process would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 3-29 and 41-64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ott *et al.*.

The claims are drawn to a process of feeding a ruminant with various *Propionibacterium* strains.

The cited reference discloses a process of feeding a ruminant with various *Propionibacterium* strains at least one of which appears to be identical to the strains cultured in the presently claimed process or is a genetic equivalent thereof (see, e.g., Examples, Table 8). It is noted that strains HhGYOKI 1-132 and I-48 are *Propionibacterium* strains. At least one of the referenced microorganisms appear to be identical to the presently claimed strains at least with respect to genetic equivalents and the disclosed process of feeding is considered to anticipate the claimed process since the *Propionibacterium* strains used in the process are disclosed as having

similar beneficial effects on ruminants when added to feed and are of the same class as that of the microorganisms cultured herein.. Consequently, the claimed process appears to be anticipated by the reference. The proliferation of the bacteria, as well as the effects on milk productivity, its content of fat, protein etc., and of increasing energy balance, plasma leptin level and plasma non-esterified fatty acid levels in the animal is inherent in the process of feeding certain *Propionibacterium* strains.

In the alternative, even if at least one of the claimed microorganisms is not identical to at least one of the the referenced microorganism with regard to some unidentified characteristics, the differences between the process disclosed and that which is claimed are considered to be so slight that the referenced process is likely to use strains possessing the same characteristics of the claimed microorganisms and have the same effectiveness particularly in view of the similar characteristics which the microorganisms have been shown to share. Thus the claimed process would have been obvious to those skilled in the art within the meaning of USC 103.

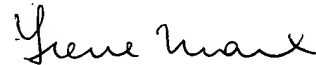
Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
Art Unit 1651